

**EPA REGISTRATION NUMBER 56783-2 – VOL. 2**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 9, 2015

Sharon M. Johnston  
Regulatory Consultant for  
Ecohealth, Inc.  
56 Hawes St.  
Brookline, MA 02446

Subject: CSF Notification per PRN 98-10 – Updating the company and active ingredient information to reflect the transfer of registration in addition to including an additional source of supply of the active ingredient on the alternate CSF.  
Product Name: Mite Arrest  
EPA Registration Number: 56783-2  
Application Date: June 23, 2015  
Decision Number: 506312

Dear Ms. Johnston:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/23/2015
- Alternate CSF 1 dated 06/23/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at [gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer Urbanski".

Jennifer Urbanski, Ph.D.  
Product Manager 04  
Invertebrate & Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

# RegGuide

June 23, 2015

Document Processing Desk (NOTIF)  
Registration Division (7504P)  
Office of Pesticide Programs  
US Environmental Protection Agency  
Room S-4900; One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

ATTN: Jennifer Urbanski  
Product Manager 4

SUBJECT: Submission of Notification Per PR Notice 98-10 – Submission of UPDATED Basic and NEW Alternate #1 Confidential Statements of Formula - alternate source of active ingredient Mite Arrest; EPA Reg. No. 56783-2

Dear Dr. Urbanski:

Enclosed, please find two originally signed updated basic and new Alternate #1 Confidential Statements of Formula for the above-subject product. We have also included a formulator's exemption statement as well as a copy of the current basic CSF to facilitate review.

The basic CSF has been revised to update the active ingredient information (supplier address and EPA Reg. No.) pursuant to the transfer of this registration from [REDACTED]

Alternate formulation #1 is being added to include an additional source of supply of the active ingredient.

If you have any questions or need additional information, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston  
Regulatory Consultant

Enclosures

cc: A. Ganak; EcoHealth

\*Product ingredient source information may be entitled to confidential treatment\*



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 56783-2	2. EPA Product Manager Jennifer Urbanski	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Mite Arrest	PM# 4	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes St. Brookline, MA 02446  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation: Use additional page(s) if necessary. (For section I and Section II.)**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

NOTIFICATION OF ALTERNATE SOURCE OF ACTIVE INGREDIENT PER PR NOTICE 98-10

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
				<input checked="" type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2.5 lbs	5. Location of Label Directions <input checked="" type="checkbox"/> on label			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title Regulatory Consultant		Telephone No. (Include Area Code) 636-942-2583	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					E. Date Application Received  <b>(Stamped)</b>
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Sharon M. Johnston		5. Date June 23, 2015			



United States  
Environmental Protection Agency  
Washington, DC 20460

**Formulator's Exemption Statement**  
(40 CFR 152.85)

<b>Applicant's Name and Address</b>  EcoHealth, Inc. 56 Hawes St. Brookline, MA 02446	<b>EPA File Symbol/Registration Number</b>  56783-2
	<b>Product Name</b>  Mite Arrest
	<b>Date of Confidential Statement of Formula (EPA Form 8570-4)</b>  June 23, 2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Permethrin

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.


(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Permethrin	[REDACTED]	[REDACTED]
	OR	OR
Permethrin	[REDACTED]	[REDACTED]
<b>Signature</b> 		
<b>Name and Title</b> Sharon M. Johnston / Regulatory Consultant		<b>Date</b> June 23, 2015

# Material Sent for Data Extraction

Reg. # SG783-2

Description: \_\_\_\_\_

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 3/11/14

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 11/4/13

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Urbanski

Phone: 347-0156 Division: RD

Date: 3/11/14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Sharon Johnston  
EcoHealth, Inc.  
56 Hawes Street  
Brookline, MA 02446

MAR 11 2014

Subject: Amended Reregistration Label  
Product Name: Mite Arrest  
EPA Registration Number: 56783-2  
EPA Decision Numbers: 413309

Dear Ms. Johnston:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the permethrin RED, and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

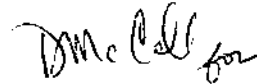
- Basic CSF, dated 11/4/13

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever

occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Dr. Jennifer Urbanski at 703-347-0156 or [urbanski.jennifer@epa.gov](mailto:urbanski.jennifer@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "R. Gebken" with a stylized flourish at the end.

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

*Enclosures: Label stamped "Accepted"*  
*Acute Toxicity Review, dated 7/20/11*  
*Product Chemistry Review, dated 11/26/13*



# MITE ARREST®

## INSECTICIDAL BEDDING FOR LABORATORY RODENTS

For Laboratory, Commercial or Veterinary Use

Permethrin impregnated cotton bedding to control mite infestations on laboratory rodents.

### Active Ingredient:

Permethrin*	7.4%
Other Ingredients:	92.6%
Total	100.00%

\*Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

EPA Reg. No. 56783-2

EPA Est. No.

Keep Out of Reach of Children

### CAUTION

### First Aid

If Swallowed	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
If in Eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information.

See side [back] panel for additional precautions.

ACCEPTED

MAR 11 2014

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for the  
pesticide registered under:

EcoHealth, Inc.  
56 Hawes Street  
Brookline, MA 02446  
(617) 742-2400

EPA. Reg. No: 56783-2

## PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

**CAUTION:** Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear long sleeved shirt, long pants, socks, shoes and gloves.

#### User Safety Recommendations:

- User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Wash the outside of gloves before removing. Then wash thoroughly and put on clean clothing.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**APPLICATION INSTRUCTIONS:** Place MITEARREST bedding directly in rodent cage to be treated. Use 2-3 MITEARREST balls per week for each rodent. Avoid wetting the MITEARREST bedding; to prevent cage flooding, care should be taken to place MITEARREST bedding away from the water bottle spout. Replace soiled MITEARREST bedding; it is recommended that fresh MITEARREST bedding be added weekly, at the time when other bedding is changed. Continue using the product for four (4) to six (6) weeks or until mites or their eggs are no longer present in the fur of rodent. As mite eggs are not affected by this treatment, extended use of the product (until all eggs have hatched or are no longer present) will provide greater long-term control and prevent reinfestation.

**NOTE:** This product contains a pyrethroid insecticide which the caged animal may ingest or come into dermal contact with. Researchers should consider the possible effects of contact with this insecticide before using the product.

### Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store at room temperature.

**Pesticide Disposal and Container Handling:** If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Net Weight:

## Urbanski, Jennifer

---

**From:** SJohns1825@aol.com  
**Sent:** Wednesday, February 26, 2014 10:53 AM  
**To:** Urbanski, Jennifer  
**Subject:** Re: 56783-2  
**Attachments:** 56783-2 label 02-26-2014.doc

Jennifer,

No problem. Let me know if you see anything else.

Sharon

In a message dated 2/26/2014 9:41:57 A.M. Central Standard Time, urbanski.jennifer@epa.gov writes:

Hi Sharon, so sorry, I misspoke! I had mistakenly read that you were including gloves (which makes sense), but that you were also keeping the socks and shoes. Can you please add those back in, it's part of the baseline PPE, thanks! I'll send the revised label to the PM for final review then.

---

**From:** SJohns1825@aol.com [mailto:SJohns1825@aol.com]  
**Sent:** Wednesday, February 26, 2014 10:33 AM  
**To:** Urbanski, Jennifer  
**Subject:** Re: 56783-2

Jennifer,

Attached is a revised label. As for the Storage & Disposal statements, since this is a non-dilutable formulation, the only statements required are the "Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available." I did remove the "Never place unused product down any indoor or outdoor drain." I'm not sure that's needed for cotton balls. I also removed "Place in trash or". All other changes have been made.

Please let me know if you have any additional changes or comments.

Thanks!

Sharon M. Johnston  
RegGuide  
509 Tower Valley Drive  
Hillsboro, MO 63050  
TEL: (636) 942-2583  
Cell: (314) 520-8554  
Fax: (636) 948-9720

e-mail: [Johnston@RegGuide.net](mailto:Johnston@RegGuide.net)  
OR [sjohns1825@aol.com](mailto:sjohns1825@aol.com)

In a message dated 2/26/2014 7:09:00 A.M. Central Standard Time, [urbanski.jennifer@epa.gov](mailto:urbanski.jennifer@epa.gov) writes:

Hi Sharon, that's fine, thanks!

---

**From:** [SJohns1825@aol.com](mailto:SJohns1825@aol.com) [<mailto:SJohns1825@aol.com>]  
**Sent:** Tuesday, February 25, 2014 10:50 AM  
**To:** Urbanski, Jennifer  
**Subject:** Re: 56783-2

Jennifer,

Just one quick question. In the User Safety Recommendations it says to wash gloves before removing but gloves are not listed in the Precautionary Statements. Also, this product is treated cotton balls, I wouldn't think any PPE would be that useful except for gloves so the last sentence of the User Safety Recommendations (except for the glove statement) seems a bit much.

What about using the following?

Under Precautionary Statements - "Wear long-sleeved shirt, long pants and gloves."

In the User Safety Recommendations:

"User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Wash the outside of gloves before removing. Then wash thoroughly and put on clean clothing."

Let me know if this is OK or if you'd like something different.

Thanks!

Sharon M. Johnston  
RegGuide  
509 Tower Valley Drive  
Hillsboro, MO 63050  
TEL: (636) 942-2583  
Cell: (314) 520-8554  
Fax: (636) 948-9720  
e-mail: [Johnston@RegGuide.net](mailto:Johnston@RegGuide.net)  
OR [sjohns1825@aol.com](mailto:sjohns1825@aol.com)

In a message dated 2/25/2014 9:14:52 A.M. Central Standard Time, [urbanski.jennifer@epa.gov](mailto:urbanski.jennifer@epa.gov) writes:

Hi Sharon, please see labeling comments based on the RED/acute tox/PC reviews for the above product. Let me know if you have any questions, thanks!

1) Based on toxicity ranking per the acute toxicity review, the First Aid statements should be placed on the label in the following order:

“IF SWALLOWED:...

IF IN EYES:...

IF ON SKIN OR CLOTHING:...” [note that this one is needed based on the acute tox review, but you can keep it)

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

“CAUTION: **Harmful if swallowed. Causes moderate eye irritation.** Avoid contact with eyes or clothing. Wear long sleeved shirt and long pants, socks and shoes.”

3) Add User Safety Recommendations to the label and place in a box:

“User Safety Recommendations

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

4) The Storage and Disposal section should be revised as follows: The subheading "Disposal" should be changed to "**Pesticide Disposal and Container Handling**." The subheading "Storage" should be changed to "Pesticide Storage". The first sentence in the box should state "Do not contaminate water, food, or feed by storage or disposal." Check PR Notice 2007-4 ([http://www.epa.gov/PR\\_Notices/pr2007-4.pdf](http://www.epa.gov/PR_Notices/pr2007-4.pdf)) to be sure that your disposal statements are compliant.

Jennifer Urbanski, Ph.D., Biologist

Insecticide-Rodenticide Branch, S7221  
Registration Division (7505P)  
U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW  
Washington, DC 20460

(703) 347-0156

# DATA PACKAGE BEAN SHEET

Date: 26-Dec-2013

Page 1 of 1

Decision #: 413309

DP #: (416931)

NON PRIA

Parent DP #:

Submission #: 873977

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 56783-2 - MITE ARREST

Company: 56783 - ECOHEALTH, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonnie Adler BADLER

Sent Date: 06-May-2010

PRIA Due Date: 05-May-2010

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (676) Product Reregistration Decision;

Ingredients: 109701, Permethrin(7.4%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 26-Dec-2013

Due Back:

DP Ingredient: 109701, Permethrin

DP Title: Final pkg for 56783-2 permethrin

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date:

Team Name: RM 10

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

This permethrin product is recommended for final reregistration based on your review of the attached preliminary label assessment, along with PC and tox reviews for case 2510. The permethrin PDCI called in Efficacy for Impregnated Fabrics & ORMS as well as Companion Animal Safety data.

According to the Registrants Response form for this product:

Efficacy/Impregnated Fabrics [810.3300] were marked as "not applicable" (#8).

Efficacy/ORMS [810.3500] was marked as "not applicable" (#8).

Companion Animal Safety [870.7200] was marked as "not applicable" (#8).

Once you have made your decision, please put all pertinent information in the product jacket. Please contact Bonnie Adler with questions.

Date: December 16, 2013

Reg. No.: 56783-2

Product Name: Mite Arrest

PM Name/Number: Richard Gebken, Risk Management Team 10

Primary Reviewer: Shirley Keel

Secondary Reviewer: Linda Arrington

New label or date of RD amended label: Received on 5/5/10

Active Ingredient(s) Assessed: Permethrin/109701

Formulation Type: Impregnated Materials

Other ai's in product

Name/PC code: N/A

Reregistration Status or Registration Date: N/A

Note to PM:

1) RD should ensure that the Storage and Disposal Section is in compliance with PR Notice 2007-4.

Assessment can be found in N:\RMIBV\label\056783\002

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1) Based on toxicity ranking per the acute toxicity review, the First Aid statements should be placed on the label in the following order:

"IF SWALLOWED:...

IF IN EYES:...

IF ON SKIN OR CLOTHING:..."

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

**"CAUTION: Harmful if swallowed. Causes moderate eye irritation.** Avoid contact with eyes or clothing. Wear (specify protective eyewear, if appropriate). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco **or using the toilet.**"

3) User Safety Requirements text must be added to the label:

**"User Safety Requirements**



Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."

4) User Safety Recommendations must be added to the label and placed in a box:

"User Safety Recommendations

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

5) The Storage and Disposal section needs a minor revision. Per Label Review Manual of January 2012, the subheading "Disposal" should be changed to "**Pesticide Disposal and Container Handling.**"

DATE OUT: 26/NOV/2013

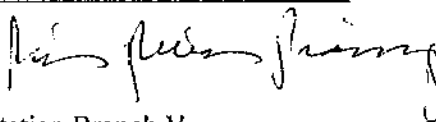
SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [ ]; EUP [X]

BARCODE NO.: D415896 REG./FILE SYMBOL NO.: 56783-2

PRODUCT NAME: MITE ARREST® MRID #s: 490818-01, 487198-02

COMPANY NAME: Ecohealth, Inc. ACTION CODE: 676

FROM: Maria Rivera Piansay, Chemist  
Product Chemistry Team  
Risk Management and Implementation Branch V  
Pesticide Re-evaluation Division (7508P)



TO: Bonnie Adler, CRM  
Risk Management and Implementation Branch V  
Pesticide Re-evaluation Division (7508P)

**INTRODUCTION:**

With this resubmission, in response to our review, dated 08/06/13, the registrant provided a revised Confidential Statement of Formula (CSF) for the basic formulation, dated 11/04/2013; a revised EPA Form 8570-35 (Data Matrix), dated 11/04/2013; and is citing product chemistry data in MRID Nos. 490818-01 and 487198-02. The registrant is requesting reregistration of their product, EPA Reg. No. 56783-2.

**FINDINGS:**

1. EPA Reg. No. 56783-2 is an end-use rodenticide product containing the active ingredient, Permethrin, with a label claim nominal concentrations of 7.4%. The product is produced by a non-integrated system.
2. The CSF for the basic formulation (now dated 11/14/2013), had been revised as requested. The revision involved changing the Density in box number 7 to match the data in the report. The CSF is now filled out correctly and completely and is now acceptable for reregistration of the subject product.
3. The cited Storage Stability data presented in MRID No. 490818-01 are acceptable to support this product. The study was conducted with a substantially-similar product Reg. No. 56783-1. The study was reviewed and accepted on 05/07/2013 under DP 411211. The requirements concerning Guideline 830.6317 (Storage Stability) are now satisfied.
4. The registrant is again referencing the data previously submitted regarding the Corrosion Characteristics of the product which was found unacceptable in the earlier review. Upon re-evaluation of the study, the PRD/RMIB V will allow the registrant to cite this study (MRID number 487198-02). The data may be used to support the reregistration of this product. The requirements pertaining to GRN 830.6320 are now satisfied.

5. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. It appears that there are no physical or chemical hazards anticipated for this product. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

NOTE TO PM: The Storage and Disposal section should be evaluated for compliance with PR Notice 2007-4.

**CONCLUSIONS:**

The registrant has now satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 56783-2.

DATE OUT: 06/AUG/2013

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [ ]; EUP [X]

BARCODE NO.: D413690

REG./FILE SYMBOL NO.: 56783-2

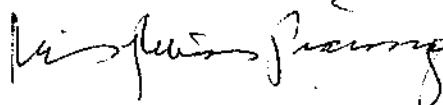
PRODUCT NAME: MITE ARREST®

MRID #s: 00164297, 480853-01, 487198-01, -02

COMPANY NAME: Ecohealth, Inc.

ACTION CODE: 676

FROM: Maria Rivera Piansay, Chemist  
 Product Chemistry Team  
 Risk Management and Implementation Branch V  
 Pesticide Re-evaluation Division (7508P)



TO: Bonnie Adler, CRM  
 Risk Management and Implementation Branch V  
 Pesticide Re-evaluation Division (7508P)

**INTRODUCTION:**

A revised Reregistration Eligibility Decision (RED), Case number 2510, was issued in May 2009 for the Active Ingredient (AI) Permethrin. According to the RED, the generic data base supporting the reregistration of Permethrin has been reviewed and found to be substantially complete. [Additional generic data are required to confirm the reregistration eligibility decision documented in the RED.]

In the 8-month response to the Permethrin RED, the registrant provided a Confidential Statement of Formula (CSF) for the basic formulation, dated 04/30/2010; EPA Form 8570-35 (Data Matrix), dated 03/14/2013; a draft label (dated 05/05/10;) and product chemistry data in MRID Nos. 00164297, 480853-01, 487198-01, and -02. The registrant is requesting reregistration of their product, EPA Reg. No. 56783-2.

**FINDINGS:**

1. EPA Reg. No. 56783-2 is an end-use rodenticide product containing the active ingredient, Permethrin, with a label claim nominal concentrations of 7.4%. The product is produced by a non-integrated system.
2. Due to an inconsistent Density data between the CSF and the report, the CSF for the basic formulation is not acceptable at this time. The Density is reported as specific gravity of 1.5 in the CSF and 0.15 g/cotton in MRID 00164297. The registrant may choose to revise the CSF to be consistent with the data in the study or submit a study that supports the specific gravity data presented in the CSF.

Other information on the CSFs is acceptable. The nominal concentration of the active ingredient agrees with that on the draft label. The certified limits for the active ingredient and inert ingredient are acceptable in accordance with 40 CFR §158.175(b)(2). All ingredients listed on the CSFs are cleared for use in pesticide formulations.

3. Except for Finding 4, the data reported in MRID Nos. 00164297, 480853-01, 487198-01, and -02 satisfy the product chemistry requirements under Subgroups A and B, which pertain to Product Identity, Composition, and Analysis, and Physical and Chemical Properties, respectively.

4. The requirements concerning Guideline 830.6317 (Storage Stability) and Guideline 830.6320 (Corrosion Characteristics) are not satisfied. The cited study in MRID number 487198-01 and -02 were conducted for 14 days at 40°C. Current regulations require this study to be conducted for one year at room temperature or using the alternate method – accelerated study for 14 days at 54°C. Additionally, the concentration of the active ingredient used in the study (approximately 5%) is too different from that in the subject product (7.4%). A note in MRID number 00164297 states that a 30-day accelerated stability study on this product was initiated on the week of 13 October 1986. If this study was conducted at an elevated temperature range of 50- 54°C, the registrant should submit this study for review. Otherwise, a new accelerated test or a one-year study must be conducted on the subject product.
5. The Enforcement Analytical Method for the determination of active ingredient content in the product is presented in MRID Nos. 00164297 and 480853-01. The method is adequate and satisfies the requirements under Guideline 830.1800.
6. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. It appears that there are no physical or chemical hazards anticipated for this product. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

#### **CONCLUSIONS:**

Except for Findings 2 and 4, the registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. **56783-2**.

**Product Chemistry Data****Subgroup A: Guideline Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)****Product Identity, Composition, and Analysis**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>40 CFR §</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
830.1550 Product Identity and Composition	158.320	480853-01	Y
830.1600 Description of Materials Used to Produce the Product	158.325	480853-01	Y
830.1620 Description of Production Process	158.330	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1650 Description of Formulation Process	158.335	480853-01	Y
830.1670 Discussion of Formation of Impurities	158.340	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1700 Preliminary Analysis	158.345	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1750 Certified Limits	158.350	480853-01	Y
830.1800 Enforcement Analytical Method	158.355	480853-01	Y

**Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310)****Physical and Chemical Properties**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>Value or Qualitative Description</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.6302 Color	White	00164297	Y
.6303 Physical State	Solid	00164297	Y
.6304 Odor	"None (when dry)"	00164297	Y

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6314 Oxidation/ Reduction: Chemical Incompatibility	NA – contains no oxidizing or reducing agents.	Data Matrix	NA
.6315 Flammability/Flame Extension	NA – contains no flammable components.	CSF	NA
.6316 Explodability	NA – contains no explosive components.	00164297	NA
.6317 Storage Stability	(See Finding 4)	00164297, 487198-01	N
.6319 Miscibility	Not applicable. The product is not intended to be diluted with petroleum solvents.	Data Matrix	N/A
.6320 Corrosion Characteristics	No corrosion present on packing material after 14 days of storage at 40°C (plastic bag)	487198-02	N (See Finding 4)
.6321 Dielectric Breakdown Voltage	Not for use around electrical equipments.	Data Matrix	NA
.7000 pH	NA - Not dispersible with water	Data Matrix	NA
.7100 Viscosity	NA - Solid		NA
.7300 Density/Relative Density	Specific gravity: 0.15g/cotton ball  Specific gravity: 1.5 (CSF)	00164297	N

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable;  
G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived; NR = Not required



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 20, 2011

MEMORANDUM:

Subject: EPA Reg. No.: 56783-2 / Mite Arrest  
DP Barcode: 391064  
Case No.: 2510

From: Jolene Trujillo, Biologist *Jolene E. Trujillo*  
Risk Management and Implementation Branch V (7508P)  
Pesticide Re-evaluation Division

To: Bonnie Adler, CRM  
Risk Management and Implementation Branch V (7508P)  
Pesticide Re-evaluation Division

Applicant: EcoHealth, Inc.  
33 Mt. Vernon St.  
Boston, MA 02108

FORMULATION FROM EPA Reg. No. 56783-2 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Permethrin .....	7.4%
<u>Other Ingredient(s):</u> .....	92.6%
Total	100.0%



**BACKGROUND:** In the 8 month response to the Permethrin RED, the registrant has cited acute toxicity studies to support the reregistration of their product, EPA Reg. No. 56783-2. The MRID's are as follows: 437997-01 (81-1), 437997-02 (81-2), 437997-03 (81-3), 478799-01 (81-4, waiver), 448338-01 (81-5), 438938-01 (81-6). Studies 81-1 and 81-2 were conducted by Biosearch Inc., 81-3 and 81-6 by Stillmeadow Inc., and 81-5 by AgrEvo UK Limited. The test material used in each of the studies was EPA Reg. No. [REDACTED]. These studies were previously reviewed by RMIBV/PRD on 06/22/10 and found acceptable.

The registrant provided a waiver request in MRID No. 478799-01 for primary eye irritation. Based on the use of the product and information presented in the waiver request, the Agency agrees that eye irritation exposure potential is minimal, though still possible, therefore a toxicity category III classification is expected to provide adequate protection.

**RECOMMENDATIONS:**

- The acute toxicity waiver and studies cited are acceptable to support the reregistration of EPA Reg. No. 56783-2.

The acute toxicity profile for EPA Reg. No. 56783-2 is currently:

Acute Oral	III	Cited
Acute Dermal	IV	Cited
Acute Inhalation	IV	Cited
Primary Eye	III	Cited
Primary Dermal	IV	Cited
Skin Sensitization	non sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

**LABELING:**

**ID #:** 56783-2 / Mite Arrest

**SIGNAL WORD:** CAUTION

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear long sleeved shirt and long pants, socks and shoes.

**FIRST AID:**

**IF SWALLOWED:** Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove

contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**USER SAFETY RECOMMENDATIONS:**

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## Adler, Bonnie

---

**From:** SJohns1825@aol.com  
**Sent:** Monday, November 04, 2013 12:11 PM  
**To:** Adler, Bonnie  
**Cc:** ariana@damminix.com  
**Subject:** 56783-2 PC Review dated Aug. 6, 2013  
**Attachments:** 56783-2 data matrix & CSF 11-4-2013.pdf; 56783-2 PC review 08-06-2013.pdf

Bonnie,

In response to the subject product chemistry review dated August 6, 2013 (your letter dated October 24, 2013), I have attached (in one document) a revised CSF and data matrix for this product.

A new storage stability & corrosion characteristics study was conducted on Damminix; 56783-1 and was found acceptable by EPA. The subject product is identical in formulation so this same study (MRID No. 49081801) is being cited on the attached data matrix for 56783-2.

As for the corrosion characteristics study (MRID No. 48719802) we disagree with the reviewer's finding that this study was not conducted in accordance with current regulations. The study was conducted in accordance with the guideline in affect at the time. This study was completed on January 13, 2012. The guidelines at that time specified a temperature range of 40 - 54 deg. C. The new guidelines specifying 54 +/- 2 deg. C were not in effect until November 16, 2012.

Please let me know if you need anything further.

Sharon M. Johnston  
RegGuide  
509 Tower Valley Drive  
Hillsboro, MO 63050  
TEL: (636) 942-2583  
Cell: (314) 520-8554  
Fax: (636) 948-9720  
e-mail: [Johnston@RegGuide.net](mailto:Johnston@RegGuide.net)  
OR [sjohns1825@aol.com](mailto:sjohns1825@aol.com)




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: November 4, 2013		EPA Reg No./File Symbol: 56783-2		Page: 1 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Mite Arrest			
Ingredient: Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830 1550	Chemical Identity	48085301	EcoHealth	OWN	
61-2/830 1600 & 830 1650	Beginning Materials & Manufacturing Process	48085301	EcoHealth	OWN	
61-3/830 1670	Discussion of Formation of Impurities	48085301	EcoHealth	OWN	
62-1/830 1700	Preliminary Analysis				Not a regulated system
62-2/830 1750	Certification of Ingredient Limits	48085301	EcoHealth	OWN	
62-3/830 1800	Analytical Method to Verify Certified Limits	48085301	EcoHealth	OWN	
63-2/830 6302	Color	164297	EcoHealth	OWN	
63-3/830 6303	Physical State	164297	EcoHealth	OWN	
63-4/830 6304	Odor	164297	EcoHealth	OWN	
63-5/830 7200	Melting Point				NA - EP
63-6/830 7220	Boiling Point				NA - EP
63-7/830 7300	Density, Bulk Density or Specific Gravity	164297	EcoHealth	OWN	
63-8/830 7840 & 830 7860	Solubility				NA - EP
63-9/830 7950	Vapor Pressure				NA - EP
63-10/830 7370	Dissociation Constant				NA - EP
Signature: 			Name and Title: Sharon M. Johnston Regulatory Consultant		Date: 11-04-2013

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DATA MATRIX

Date: November 4, 2013		EPA Reg No./File Symbol: 56783-2		Page 2 of 3	
Applicant's/Registrant's Name & Address: EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product: Mite Arrest			
Ingredient: Permethrin					
Guideline Reference Number	Guideline Study Name	MRIID Number	Submitter	Status	Note
63-11/830 7570	Octanol Water Partition Coefficient				NA - EP
63-12/830 7000	pH				NA - not applicable with agent
63-13/830 6313	Stability				NA - EP
63-14/830 6314	Oxidizing/Reducing Action				NA - not applicable to this chemical category
63-15/830 6315	Flammability	164297	EcoHealth	OWN	
63-16/830 6316	Explosibility				NA - not potentially explosive
63-17/830 6317	Storage Stability	49081801	EcoHealth	OWN	
63-18/830 7100	Viscosity				NA - solid
63-19/830 6319	Miscibility				NA - not applicable with petroleum products
63-20/830 6320	Corrosion Characteristics	48719802	EcoHealth	OWN	
63-20/830 6320	Corrosion Characteristics	49081801	EcoHealth	OWN	
63-21/830 6321	Dielectric Breakdown Voltage				NA - not for use as an electrical insulator
81-1/870 1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870 1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870 1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
Signature: 			Name and Title: Sharon M. Johnston Regulatory Consultant		Date: 11-04-2013



### DATA MATRIX

Page 3 of 3

Product	Mile Arrest
---------	-------------

Ingredient	Permethrin
------------	------------

Date  
11-04-2013



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DATA MATRIX

Date November 4, 2013


EPA Reg No./File Symbol 56783-2

Page 1 of 3

Applicant's/Registrant's Name & Address  
EcoHealth, Inc.  
56 Hawes Street  
Brookline, MA 02446

Product  
Mile Arrest

Ingredient Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
Signature			Name and Title Sharon M. Johnston Regulatory Consultant		Date 11-04-2013




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DATA MATRIX

Date: November 4, 2013		EPA Reg No./File Symbol: 56783-2		Page 2 of 3	
Applicant's/Registrant's Name & Address: EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product:  Mite Arrest			
Ingredient: Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Valent BioSciences Corporation		
			EcoHealth	OWN	
			EcoHealth	OWN	
			EcoHealth	OWN	
			EcoHealth	OWN	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
Signature: 			Name and Title: Sharon M. Johnston Regulatory Consultant		Date: 11-04-2013






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## DATA MATRIX

Date November 4, 2013		EPA Reg No./File Symbol 56783-2		Page 3 of 3	
Applicant's/Registrant's Name & Address		Product			
EcoHealth, Inc. 56 Huxins Street Brookline, MA 02446		Mito Arrest			
Ingredient	Permethrin				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			EcoHealth	OWN	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
Signature		Name and Title		Date	
		Sharon M. Johnston Regulatory Consultant		11-04-2013	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 24 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**CERTIFIED MAIL**

Sharon Johnston, agent for EcoHealth, Inc.  
RegGuide  
509 Tower Valley Drive  
Hillsboro, MO 63050

**Subject:** Product Chemistry Review for the Permethrin Reregistration Eligibility Decision Document (RED), April 2006  
**EPA Reg. No. 56783-2**

Dear Ms. Johnston;

The Agency has reviewed the product chemistry data you have submitted to support the Permethrin RED. The Confidential Statement of Formula (CSF) is not acceptable because the density value on the CSF varies from the submitted data. Therefore the guideline requirement for density (830.7300) is not acceptable. You may revise the CSF or submit new data to resolve this discrepancy. In addition, the submitted storage stability and corrosion characteristics study (guidelines 830.6317 and 830.6320) is not acceptable. New regulations for an accelerated study require 14 days at 54°C. In study 00164297, it was noted that a 30 day accelerated study was conducted in 1986. If this study is available for review, please submit it for review. Alternatively, a new on-year study or an accelerated test must be submitted. Please refer to the enclosed review for details.

You must submit the outstanding data and any revisions to your CSF to the Agency within 10 days of receipt of this letter. If new data are to be conducted, a time extension request must be submitted to the Agency within the same time frame. A copy of the review is enclosed. If you have any questions, please call me at 703-308-8523.

Sincerely,

A handwritten signature in cursive script that reads "Bonnie Adler".

Bonnie Adler  
Risk Management and Implementation Branch V  
Pesticide Re-Evaluation Division

enclosure



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 56783-2	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Mite Arrest	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 01-11-2013	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - Submission of Storage Stability data

e-mail: Johnston@RegGuide.net

Fax: (636) 948-9720

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title Regulatory Consultant		Telephone No. (Include Area Code) (636) 942-2583	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Sharon M. Johnston		5. Date March 14, 2013			




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DATA MATRIX

Date March 14, 2013		EPA Reg No./File Symbol 56783-2		Page 1 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	48085301	EcoHeath	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	48085301	EcoHeath	OWN	
61-3/830.1670	Discussion of Formation of Impurities	48085301	EcoHeath	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	48085301	EcoHeath	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	48085301	EcoHeath	OWN	
63-2/830.6302	Color	164297	EcoHeath	OWN	
63-3/830.6303	Physical State	164297	EcoHeath	OWN	
63-4/830.6304	Odor	164297	EcoHeath	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHeath	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013

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DATA MATRIX

Date March 14, 2013		EPA Reg No./File Symbol 56783-2		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHeath	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	Vol. 1 of 1	EcoHeath	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not dilutable with petroleum solvents
63-20/830.6320	Corrosion Characteristics	48719802	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 14, 2013			EPA Reg No./File Symbol 56783-2		Page 3 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446			Product Mite Arrest		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-5/870.2500	Primary Dermal Irritation	44833801	Valent BioSciences Corporation	PER	
81-6/870.2600	Dermal Sensitization	43893801	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013



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DATA MATRIX

Date March 14, 2013		EPA Reg No./File Symbol 56783-2		Page 1 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
Signature			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013





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DATA MATRIX

Date March 14, 2013		EPA Reg No./File Symbol 56783-2		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
			Valent BioSciences Corporation		
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHealth	OWN	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
			EcoHealth	OWN	
			Signature 		





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DATA MATRIX

Date March 14, 2013		EPA Reg No./File Symbol 56783-2		Page 3 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 56 Hawes Street Brookline, MA 02446		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
Signature			Name and Title Sharon M. Johnston Regulatory Consultant		Date 03-14-2013

48719800

# RegGuide

January 16, 2012

Pesticide Re-Evaluation Division (7508P)  
Office of Pesticide Programs  
US Environmental Protection Agency  
One Potomac Yard (South Building)  
2777 S. Crystal Drive  
Arlington, VA 22202

ATTN: Bonnie Adler  
Chemical Review Manager  
Permethrin; Case No. 2510; PDCI-109701-26513

SUBJECT: EcoHealth, Inc.  
Damminix®; EPA Reg. No. 56783-1  
Mite Arrest®; EPA Reg. No. 56783-2  
Submission of Storage Stability & Corrosion Characteristics data

Dear Ms. Adler:

Enclosed, please find 14-day elevated temperature storage stability and corrosion characteristics data in response to the Permethrin data call-in notice for the above-subject products. These products are identical in formulation but are marketed in different packaging.

The following materials are enclosed:

A transmittal document is attached as page 2 of this letter.

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,



Sharon M. Johnston  
Regulatory Consultant  
Agent For EcoHealth, Inc.

Enclosures

Cc: Ariana Ganak; EcoHealth

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

EcoHealth, Inc.  
33 Mt. Vernon St.  
Boston, MA 02108

2. Regulatory Action in Support of Which This Package is Submitted

Application for Re-Registration

Damminix®; EPA Reg. No.: 56783-1  
Mite Arrest®; EPA Reg. No. 56783-2

3. Transmittal Date

January 16, 2012

4. List of Submitted Studies:

<u>MRID No.</u>	<u>Volume No.</u>	<u>OPPTS Guideline No.</u>	<u>Study Title</u>
<b><u>48719801</u></b>	1 of 2	830.6317 & 6320	Physical & Chemical Characteristics of Damminix® Tick Tubes: Storage Stability and Corrosion Characteristics
<b><u>48719802</u></b>	2 of 2	830.6320	Physical and Chemical Characteristics of MITEARREST® Insecticidal Bedding For Laboratory Rodents: Corrosion Characteristics

Company Official: Sharon M. Johnston  
Regulatory Consultant  
Agent for EcoHealth, Inc.

Phone: (636) 942-2583

Signature: \_\_\_\_\_

Company Name: EcoHealth, Inc.



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 56783-2	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Mite Arrest	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - Submission of Storage Stability & Corrosion Characteristic data in response to the permethrin PDCI  
e-mail: Johnston@RegGuide.net  
Fax: (636) 948-9720

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* <b>Certification must be submitted</b>					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sharon M. Johnston	Title Regulatory Consultant	Telephone No. (Include Area Code) (636) 942-2583
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant	
4. Typed Name Sharon M. Johnston	5. Date January 16, 2012	




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 16, 2012		EPA Reg No./File Symbol 56783-2		Page 1 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	48085301	EcoHealth	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	48085301	EcoHealth	OWN	
61-3/830.1670	Discussion of Formation of Impurities	48085301	EcoHealth	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	48085301	EcoHealth	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	48085301	EcoHealth	OWN	
63-2/830.6302	Color	164297	EcoHealth	OWN	
63-3/830.6303	Physical State	164297	EcoHealth	OWN	
63-4/830.6304	Odor	164297	EcoHealth	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHealth	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 01-16-2012



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DATA MATRIX

Date January 16, 2012		EPA Reg No./File Symbol 56783-2		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHeath	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	Vol. 1 of 2	EcoHeath	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not dilutable with petroleum solvents
63-20/830.6320	Corrosion Characteristics	Vol. 2 of 2	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 01-16-2012



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Date January 16, 2012		EPA Reg No./File Symbol 56783-2	Page 3 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product  Mite Arrest	

[illegible]

Name and Title	Sharon M. Johnston Regulatory Consultant
----------------	---

Date  
01-16-2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 16, 2012		EPA Reg No./File Symbol 56783-2		Page 1 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
			EcoHeath	OWN	
Signature	Name and Title Sharon M. Johnston Regulatory Consultant			Date 01-16-2012	





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Date January 16, 2012		EPA Reg No./File Symbol 56783-2		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product  Mite Arrest			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Valent BioSciences Corporation		
			EcoHealth	OWN	
			EcoHealth	OWN	
			EcoHealth	OWN	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
EcoHealth	OWN				
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 01-16-2012




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DATA MATRIX

Date January 16, 2012			EPA Reg No./File Symbol 56783-2		Page 3 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108			Product  Mite Arrest		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Valent BioSciences Corporation	PER	
			Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 01-16-2012

# RegGuide

April 30, 2010

Product Reregistration Branch  
Pesticide Re-Evaluation Division (7508P)  
Office of Pesticide Programs  
US Environmental Protection Agency  
One Potomac Yard (South Building)  
2777 S. Crystal Drive  
Arlington, VA 22202

ATTN: Bonnie Adler  
Chemical Review Manager  
Permethrin; Case No. 2510; PDCI-109701-26513

SUBJECT: **Permethrin** – 8-Month Response to Data Call-In Notice  
EcoHealth, Inc.  
Mite Arrest®; EPA Reg. No. 56783-2

Dear Ms. Adler:

Enclosed, please find the 8-month response to the Permethrin data call-in notice for the above-subject product.


The following materials are enclosed:

- 1) Application for Registration
- 2) Formulators Exemption Statement
- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Letter of Authorization from Valent BioSciences Corporation
- 6) Data Matrix
- 7) Draft Labeling (5 copies)

Product chemistry data are being submitted concurrently under the identical formulation - Damminix (EPA Reg. No. 56783-1).

If you have any questions, please do not hesitate to contact me at (636) 942-2583.

Sincerely,




Sharon M. Johnston  
Regulatory Consultant  
Agent For EcoHealth, Inc.

Enclosures

Cc: Ariana Ganak; EcoHealth

Sharon M. Johnston, Esq.  
509 Tower Valley Drive  
Hillsboro, MO 63050



Tel: 636-942-2583  
Fax: 636-948-9720  
e-mail: Johnston@RegGuide.net



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 56783-2	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Mite Arrest	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Re-Registration - 8-month response to the permethrin PDCI

e-mail: Johnston@RegGuide.net

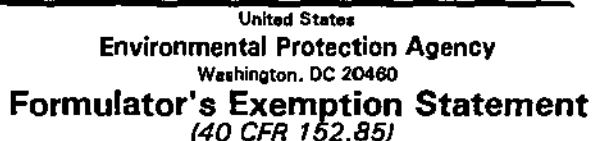
Fax: (636) 948-9720

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input checked="" type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed directly on package			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sharon M. Johnston		Title Regulatory Consultant		Telephone No. (Include Area Code) (636) 942-2583	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Sharon M. Johnston		5. Date April 30, 2010			

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number EcoHealth, Inc., 33 Mt. Vernon St., Boston, MA 02108 TEL: (636) 942-2583	EPA Registration Number/File Symbol 56783-2
Active Ingredient(s) and/or representative test compound(s) Permethrin	Date April 30, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor	Product Name Mite Arrest

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☒ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

04-30-2010

Sharon M. Johnston / Regulatory Consultant




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date April 30, 2010		EPA Reg No./File Symbol 56783-1		Page 1 of 3	
Applicant's/Registrant's Name & Address EcoHeath, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product Damminix			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/830.1550	Chemical Identity	Vol. 1 of 1	EcoHeath	OWN	
61-2/830.1600 & 830.1650	Beginning Materials & Manufacturing Process	Vol. 1 of 1	EcoHeath	OWN	
61-3/830.1670	Discussion of Formation of Impurities	Vol. 1 of 1	EcoHeath	OWN	
62-1/830.1700	Preliminary Analysis				NA - not an integrated system
62-2/830.1750	Certification of Ingredient Limits	Vol. 1 of 1	EcoHeath	OWN	
62-3/830.1800	Analytical Method to Verify Certified Limits	Vol. 1 of 1	EcoHeath	OWN	
63-2/830.6302	Color	164297	EcoHeath	OWN	
63-3/830.6303	Physical State	164297	EcoHeath	OWN	
63-4/830.6304	Odor	164297	EcoHeath	OWN	
63-5/830.7200	Melting Point				NA - EP
63-6/830.7220	Boiling Point				NA - EP
63-7/830.7300	Density, Bulk Density or Specific Gravity	164297	EcoHeath	OWN	
63-8/830.7840 & 830.7860	Solubility				NA - EP
63-9/830.7950	Vapor Pressure				NA - EP
63-10/830.7370	Dissociation Constant				NA - EP
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010




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DATA MATRIX

Date April 30, 2010		EPA Reg No./File Symbol 56783-1		Page 2 of 3	
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108		Product Damminix			
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-11/830.7570	Octanol Water Partition Coefficient				NA - EP
63-12/830.7000	pH				NA - not dispersible with water
63-13/830.6313	Stability				NA - EP
63-14/830.6314	Oxidizing/Reducing Actin				NA - contains no oxidizing or reducing agents
63-15/830.6315	Flammability	164297	EcoHealth	OWN	
63-16/830.6316	Explosibility				NA - not potentially explosive
63-17/830.6317	Storage Stability	On-going	EcoHealth	OWN	
63-18/830.7100	Viscosity				NA - solid
63-19/830.6319	Miscibility				NA - not dilutable with petroleum solvents
63-20/830.6320	Corrosion Characteristics	On-going	EcoHealth	OWN	
63-21/830.6321	Dielectric Breakdown Voltage				NA - not for use around electrical equipment
81-1/870.1100	Acute Oral Toxicity	43799701	Valent BioSciences Corporation	PER	
81-2/870.1200	Acute Dermal Toxicity	43799702	Valent BioSciences Corporation	PER	
81-3/870.1300	Acute Inhalation Toxicity	43799703	Valent BioSciences Corporation	PER	
81-4/870.2400	Primary Eye Irritation	47879901	EcoHealth	OWN	Waiver Request
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010






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DATA MATRIX

Date April 30, 2010			EPA Reg No./File Symbol 56783-1		Page 3 of 3
Applicant's/Registrant's Name & Address EcoHealth, Inc. 33 Mt. Vernon St. Boston, MA 02108			Product Damminix		
Ingredient Permethrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-5/870.2500	Primary Dermal Irritation	44833801	Valent BioSciences Corporation	PER	
81-6/870.2600	Dermal Sensitization	43893801	Valent BioSciences Corporation	PER	
Signature 			Name and Title Sharon M. Johnston Regulatory Consultant		Date 04-30-2010



# ECOHEALTH, INC.

September 9, 2009

Chemical Review Manager  
Reregistration Branch  
Special Review and Registration Division (7508P)  
Office of Pesticide Programs  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

SUBJECT: EcoHealth, Inc.; EPA Co. No. 56783  
Authorization of Company Representative

Dear Sir/Madam:

EcoHealth, Inc., 33 Mt. Vernon St., Boston, MA 02108 hereby authorizes Sharon M. Johnston of RegGuide, 509 Tower Valley Drive, Hillsboro, Missouri 63050, to act on behalf of EcoHealth, Inc. as an authorized company representative for following regulatory action(s) ONLY:

The response to and follow-up with the US Environmental Protection Agency regarding the Data Call-In Notice for Permethrin.

This authorization may be revoked at any time upon written notice. Please contact me at (617) 742-2400 if you have any questions or need additional information.

Sincerely,



Ariana Ganak, Director  
EcoHealth Inc.

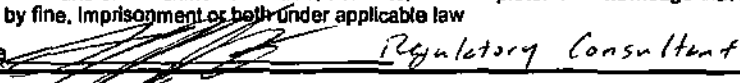
cc: Sharon M. Johnston; RegGuide

United States Environmental Protection  
Agency Washington, D.C. 20460

OMB Approval 2070-0107  
OMB Approval 2070-0057

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary.

1. Company Name and Address ECOHEALTH, INC. 33 MT. VERNON ST. BOSTON, MA 02108		2. Case # and Name 2510 Permethrin  EPA Reg. No. 56783-2		3. Date and Type of DCI and Number 28-May-2009 PRODUCT SPECIFIC ID # PDCI-109701-26513					
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<u>Product Chemistry Data Requirements (Conventional Chemical)</u>								
830.1550	Product identity and composition (32)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1600	Description of materials used to produce the product (33)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1620	Description of production process (34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.1650	Description of formulation process (35)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	1
830.1670	Discussion of formation of impurities (36)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1700	Preliminary analysis (26, 27, 37)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.1750	Certified limits (38)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.1800	Enforcement analytical method (39)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6302	Color (12)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.6303	Physical state (25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.6304	Odor (21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law							11. Date		
Signature and Title of Company's Authorized Representative  Regulatory Consultant							9-28-09		
12. Name of Company EcoHealth, Inc.							13. Phone Number 636-942-2565		

United States Environmental Protection  
Agency Washington, D.C. 20460

OMB Approval 2070-0107  
OMB Approval 2070-0057

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4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions (28,29,40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGA/	8	✓
830.6314	Oxidizing or reducing action (22)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6315	Flammability (17)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6316	Explosibility (16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6317	Storage stability of product (41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	16	✓
830.6319	Miscibility (20)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.6320	Corrosion characteristics (42)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	16	✓
830.6321	Dielectric breakdown voltage (15)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.7000	pH of water solutions or suspensions (23,24)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGA/MP/EP	8	✓
830.7050	UV/Visible absorption					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGA/PAI	8	✓
830.7100	Viscosity (30)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	✓
830.7200	Melting point/melting range (18,19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGA/	8	✓
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date	9-28-09 62	

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Agency Washington, D.C. 20460

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7220	Boiling point/boiling range (10, 11)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.7300	Density/relative density (13, 14)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	1
830.7370	Dissociation constant in water (47, 48)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
830.7550	Partition coefficient (n-octanol/water), shake flask method (49)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	8
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography (54)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	8
830.7840	Water solubility: Column elution method, shake flask method (50)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
830.7860	Water solubility, generator column method (51)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
830.7950	Vapor pressure (52, 53)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
<b>Toxicology Data Requirements (Conventional Chemical)</b>									
870.1100	Acute Oral Toxicity (1, 43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI, EP, dilute EP?	8	6
870.1200	Acute dermal toxicity (2, 3, 44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI, EP, dilute EP?	8	6
870.1300	Acute inhalation toxicity (4)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	6
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date	9-28-09	
								63	

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Agency Washington, D.C. 20460

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
870.2400	Acute eye irritation (5)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	7
870.2500	Acute dermal irritation (6,7)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	4
870.2600	Skin sensitization (8,9)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	6
870.7200	Companion animal safety (31)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	CHOICE	8	8
810.3300	Treatments to control pests of humans and pets (45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	8
810.3500	Premises treatments (46)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	8
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date	9-28-09 64	

